

### **REMARKS/ARGUMENTS**

Claims 1-31 are pending in the present application. Claims 24-31 have been withdrawn from consideration and may be made the subject of divisional or continuation applications, to be filed at any time during the pendency of the present application. No amendments have been made. Applicants respectfully request reconsideration of the subject application. This response is submitted in response to the Office Action dated August 21, 2009 and the Advisory Action dated November 16, 2009.

### **STATUS OF THE CLAIMS**

Claims 1, 13-17 are rejected under 35 U.S.C. §102(b) (hereinafter, "Section 102(b)") as being anticipated by Usala (U.S. Pat. No. 5,236,703, hereinafter "Usala").

Claims 1-8, 10, 13-17 are rejected under 35 U.S.C. § 103(a) (hereinafter, "Section 103(a)") as being unpatentable over Milner (U.S. Pat. No. 5,031,245, hereinafter "Milner") in view of Fechner et al. (U.S. Pat. No. 7,241,459, hereinafter "Fechner"), Usala and Wollmann et al. (U.S. Pat. No. 3,793,059, hereinafter "Wollmann").

1-23 are rejected under Section 103(a) as being unpatentable over Milner in view of Fechner, Usala, Wollmann and Chou ( U.S. Publication 2003/0204893, hereinafter "Chou").

Applicants respectfully traverse all rejections and requests reconsideration for all of the pending claims in light of the amendments to the claims.

### **Rejection Under Section 102(b): Usala**

#### **Response to Examiner's points in Office Action on page 3 and Advisory Action**

Claims 1, 13-17 are rejected under Section 102(b) as being anticipated by Usala. Claims 1 and 18 had been previously amended in order to clarify an embodiment of the present invention in which the material forming the second (inner) layer does not include the antimicrobial agent of the first (outer) layer.

Examiner has maintained the previous rejection and in the Advisory Action, is believed to have impermissibly read Applicant's other embodiments into the claims. As noted, claim 1 recites in part, "a second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer,". An embodiment where the layer is "**without**" the antimicrobial agent from the first layer is being claimed. If the Usala reference teaches, "some", a "low amount", "different amounts", then it cannot anticipate Applicant's claim limitation which requires "without", and therefore fails to teach each and every claim limitation as required to anticipate claim 1.

The Advisory Action states that:

"USALA teaches multiple article may have different amount of the agent in each layer (see col. 4, line 20-21), wherein for a small group of people having allergic reaction to povidone iodine, the glove can be constructed with no release on the inner surface (see col. 4, line 54-57); this it would have been inherent to have zero amount in the 'no release' layer to prevent allergic reactions". (See Advisory Action, continuation sheet).

Applicant respectfully disagrees. It is NOT "inherent" that Usala teaches, discloses or suggests a layer formed with zero amount. Usala must be considered in its entirety, including disclosures that teach away from the claims. Examiner has not shown that the claimed glove material formed without the agent "necessarily flows from the teachings of the applied prior art". (MPEP Section 2112) Usala provides no inherency in a glove material formed "without" the antimicrobial agent and to the contrary, is inherently teaching some amount for either a controlled release or preventing a nidus of infection while in storage. The cited lines of Usala teach "different amounts" and "no release". This is not the equivalent of "without". In fact, when reading "no release" in context with the disclosure of Usala, the "no release" substrate is formed by "using aged mixtures in which substantially all the povidone-iodine is chemically bound with the latex. Such a layer, while not releasing the povidone-iodine upon contact with polar solutions, will nonetheless prevent a nidus of infection from developing in storage or in use."(col. 4, lines 45-53). Applicant therefore disagrees with Examiner since Usala's "different

amounts” and “no release” do not teach the claimed layer is formed “without” or “free of” the antimicrobial agent of the first layer.

Further, Usala states, this “no release substrate” as described above in terms of chemically binding the povidone-iodine with the latex, can be placed on the inner surface, for people having “a mild allergic reaction to povidone iodine”. There is nothing to teach, disclose or suggest that the povidone-iodine does not exist in the substrate. To the contrary, a no release substrate in which the povidone-iodine is chemically bound with the latex is disclosed in Usala. Again, it does not *necessarily* mean that Usala discloses a layer “without” any povidone-iodine, but rather only states a “no release” layer, for those with a “mild allergic reaction”. It is apparent by the definition of “no release” that the substrate is holding an amount from being released, i.e. the existing povidone-iodine within the substrate. It is rather inherent that Usala teaches a substrate with povidone-iodine. It is therefore not inherent that the second layer is structurally formed of a glove material “without the antimicrobial agent”.

In addition, the claimed limitation of “resist contact between the anti-microbial agent with the hand” is further not addressed in the Advisory Action and neither is it disclosed by Usala. Since the povidone-iodine exists, chemically bound, in the substrate, it is not taught, disclosed or suggested how it resists “contact” with the hand since the substrate is contacting the hand. Rather, the Advisory Action states that Usala allegedly “prevents allergic reaction”, which again, is NOT what the claims recite. The claims require “resist contact between the anti-microbial agent with the hand”. Further, neither does Usala actually disclose “prevent allergic reaction”. Usala simply discloses for those with a “mild allergic reaction” the “no release” substrate can be on the inside, meaning those with a mild allergic reaction may be better suited to a no release inner surface in which the povidone-iodine is chemically bound with the latex, as opposed to a person with a severe allergic reaction. In whole, Usala fails to disclose, teach or suggest each and every claim limitation.

As reiterated, the language of claim 1 does not state “no release”, instead, the claimed language requires the second layer material NOT to have the agent from the first layer. A layer that has “no release” of a substance does not in any manner teach or inherently teach that the layer itself is formed WITHOUT that substance. Further, there is no teaching that an amount is

“zero” in Usala. If there is an amount in something, then by definition that cannot be “zero”. Usala’s “no release” of a substance yet, which is chemically bound and existing in the layer is by definition containing an amount of the substance. Examiner has also improperly imported the limitations of another embodiment from Applicant’s specification in par. 0063 for examination against Usala, and not the required claim language. The claims do not recite a layer not including “as high a proportion” as Examiner is reading into the claim. The claims recite that the layer is formed “without” the agent from the first layer. Accordingly, Usala, fails to teach each and every claim limitation of the claims and rather teaches away from the “without” requirement by continuously teaching “control release” of the substance.

Finally, the conventional methods referred to by Examiner in col. 4 line 40 of Usala are in no manner teaching of the claim limitations. Usala, in stating “in such instances” is specifically referring to making a dentist’s gloves which again, have a “minimal release” (not claimed) and further in which the layer discussed is the *outer layer*, and not the relevant second layer (inner layer) closest to the user’s hand as claimed by Applicant.

For at least these reasons, Usala does not anticipate Applicant’s claims.

Applicant respectfully reiterates that, in review of the Usala reference, there is no teaching found which anticipates each and every claim limitation of claim 1. In particular, previously amended claim 1 recites in part,

“A disposable protective glove comprising: a first layer of glove material, with an effective amount of antimicrobial agent therein the glove material or thereon an outer surface of the first layer; and a second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer, to be closer to a hand than the first layer, when the glove is worn on the hand, the second layer configured to resist, when the glove is worn, penetration by the anti-microbial agent and thereby to resist contact between the anti-microbial agent with the hand in part.”

Specifically, Usala does not disclose a disposable protective glove wherein, a “second layer formed of a glove material *without the antimicrobial agent from the first layer therein the second layer...*” (emphasis added). Usala describes single or multilayered surgical gloves, wherein the

latex substrate incorporates a “control releasable” antimicrobial agent that “when in contact with a polar liquid ... prevent[s] contamination, transmission or penetration by pathogens”. (Usala, col. 3, lines 56-60, 64-65). More importantly, each layer of the multilayer article of Usala may have “different amounts of the agent in each layer, and accordingly different release rates for each layer.” (Usala, col. 4, lines 20-22). In contrast to claim 1, Usala thus teaches of the same antimicrobial agent being present in different amounts in each layer of the multilayer article.

The Examiner argues that Usala’s “no release substrate inner layer would inherently resist penetration by the antimicrobial agent.” Examiner also contends that Usala’s “no release substrate equates to no antimicrobial.” Applicant respectfully disagrees with Examiner’s assertions. Claim 1 of the present invention discloses, “a second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer.” In contrast, the “no release substrate inner layer” of Usala contains the antimicrobial agent of the first layer, because it is made by “using aged mixtures in which substantially all the povidone-iodine is chemically bound with the latex.” (Usala, col. 4, lines 48-50). The “no release” layer of Usala also contains the same antimicrobial (povidone-iodine) layer of the first layer, and thus Usala does not teach that one of its layers closer to the skin is configured to resist penetration of the anti-microbial agent *from the other layer* and to resist contact with the hand. Usala thereby teaches away from a second layer *without the antimicrobial agent from the first layer* by teaching that the “povidone-iodine is chemically bound” within the material. Irregardless of placing the “no release substrate on the inner surface” for those with “mild allergic reactions”, the fact remains that there is indeed povidone iodine still mixed within the layer and this does NOT teach that the “second layer is formed” “without the antimicrobial agent from the first layer”.

Furthermore, claim 1 recites a “second layer configured to resist, when the glove is worn, penetration by the anti-microbial agent and thereby to resist contact between the anti-microbial agent with the hand in part.” Usala fails to teach this limitation. In fact, Usala contains enough of the same antimicrobial agent (povidone-iodine) in the “no release” layer to “prevent a nidus of infection from developing in storage or in use.” (Usala, col. 4, lines 52-53.) This antimicrobial agent in Usala “while not releasing upon contact with polar solutions” is still chemically bound within the inner layer and although described as a “no release” layer does not teach the agent

already within is resisted from contact with the hand. Being chemically bound within the layer that touches the hand teaches that the agent naturally comes in contact with the hand when worn.

Accordingly, since all the claimed limitations of claim 1 are not taught by Usala, Applicant submits claim 1 is novel and patentable. Applicant respectfully requests withdrawal of the rejection of claim 1 under Section 102(b).

#### Dependent Claims 13-17

Dependent claims 13-17 include all limitations of their respective base claim 1. Accordingly, Applicant respectfully submits that these dependent claims are all allowable for at least the same reasons as their base claim 1.

Applicant respectfully disagrees with any assertions regarding the dependent claims from the Office Action. Any such assertions have been made moot by the above discussion of the base claim. Applicant respectfully requests withdrawal of the rejection of claims 13-17 under Section 102(b) based on Usala.

#### **Rejection Under Section 103(a): Milner in view of Fechner, Usala and Wollmann**

Claims 1-8, 10, 13-17 were rejected under Section 103(a) as being unpatentable over Milner in view of Fechner, Usala and Wollmann. As mentioned above, claims 1, 7 and 18 have been previously amended. No new matter has been added to the claims.

In review of Milner in view of Fechner, Usala and Wollmann, there is no teaching found which anticipates each and every claim limitation of claim 1. As claims 2-8, 10, 13-17 depend from claim 1, they include all the limitations of base claim 1.

Milner has been cited for showing a glove incorporating an antimicrobial agent into the glove material. However, Milner fails in combination with the references to teach the "first layer" and the "second layer" glove structure as claimed. Contrary to Examiner's assertion, as explained above, Usala does *not* provide for the deficiencies of Milner. Usala actually does not teach a "a second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer, to be closer to a hand than the first layer, when the glove is worn

on the hand, the second layer configured to resist, when the glove is worn, penetration by the anti-microbial agent *and thereby to resist contact* between the anti-microbial agent with the hand in part". Examiner cites Usala's "no release substrate would inherently resist penetration by the anti-microbial agent", however, for reasons discussed above Usala does indeed contain povidone iodine within the material. The povidone iodine substrate of Usala, while having "no ascertainable release" nevertheless does not teach that it is "without the antimicrobial agent form the first layer" and further cannot teach resisting contact of the agent with the hand when it is chemically bound throughout the substrate. Accordingly, there is no teaching of all the claimed limitation of claim 1 when reviewing the teachings of Milner and Usala in combination.

Neither does a combination of these references with Fechner or Wollmann provide for the claimed limitations of claim 1. Fechner or Wollmann do not bear on the limitations as discussed above with regard to claim 1 as they too do not provide the required limitation of the "a second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer, to be closer to a hand than the first layer, when the glove is worn on the hand, the second layer configured to resist, when the glove is worn, penetration by the anti-microbial agent and thereby to resist contact between the anti-microbial agent with the hand in part." In combination, the references do not show each and every claim limitation of independent claim 1, and therefore fail to make a prima facie case of obviousness. In order to assess the elements of each reference, each reference must be studied to show that each reference fails to provide for all the limitations as claimed.

The combination of the references do not render claim 1 obvious since the references, at most, only show that it is concerned with an antimicrobial agent of a layer in contact with a hand and NOT with an agent of an outer first layer overlaying an inner layer from contacting the hand.

Accordingly, the references alone or in combination fail to teach each and every claim limitation of claim 1. Moreover, it would not have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate an inner layer configured to prevent the Triclosan from contacting the hand and add an additional anti-microbial and buffer agent that is an acid from an edible plant, such as salicylic acid, into Milner's glove. While Fechner teaches that Triclosan may have allergic reactions, it also teaches of other antibacterially and

fungicidally acting additives for polymers without harmful side effects. Thus one skilled in the art of making gloves with Triclosan in it would naturally think of using Fechner's new compound to contact the hand as opposed to the Applicant's claimed "second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer" as configured to resist penetration by the antimicrobial agent and contact with the hand.

As the underlying reference to Usala does not provide for the required claim element of "a second layer formed of a glove material **without** the antimicrobial agent from the first layer", the combination of the references do not establish a prima facie case of obviousness. As thoroughly discussed above, Usala teaches a layer having an amount of the agent (povidone-iodine) chemically bound within the material.

Accordingly, the references *in combination* do not show each and every limitation of claim 1. Dependent claims are therefore allowable for at least the same reasons as their base claim 1. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1-8, 10, 13 and 17 under Section 103(a).

#### **Rejection Under Section 103(a): Milner in view of Fechner, Usala, Wollmann and Chou**

Claims 1-23 were rejected under Section 103(a) as being unpatentable over Milner in view of Fechner, Usala, Wollmann and Chou. As mentioned above, claims 1, 7 and 18 have been previously amended.

The discussion above with respect to the Section 103(a) rejection against independent claim 1 is applied herewith to the rejection of claims 1-23. The additional Chou reference also does not provide for the deficiencies as mentioned above with respect to Milner and Usala and therefore not ALL the claimed limitations of independent claim 1 are taught by the combination of the references. Chou is used to allegedly show the use of aloe vera and other dependent limitations, yet, the missing elements which Usala fails to provide are still not provided. There is no teaching of a disposable protective glove having an "antimicrobial agent" of a "first layer" and a "second layer formed of a glove material without the antimicrobial agent from the first layer therein the second layer, to be closer to a hand than the first layer, when the glove is worn on the hand, the second layer configured to resist, when the glove is worn, penetration by the anti-microbial agent and thereby to resist contact between the anti-microbial agent with the



hand.” Accordingly, Applicant respectfully requests withdrawal of the rejection of claim 1 and its respective dependent claims under Section 103(a).

#### Independent claim 18

Claim 18 and its dependent claims are also allowable over Milner in view of Fechner, Usala, Wollmann and Chou for similar reasons. Claim 18 recites in part “an inner layer to be closer to the skin than the outer layer, the inner layer being free of said antimicrobial agent of the outer layer and having less proteins than natural rubber latex and comprising an interior surface with a skin conditioning or soothing substance dispersed thereon; wherein the inner layer serves as a barrier between the skin and the outer layer so to resist developing of antimicrobial resistance in microbes on the skin and some of the skin conditioning or soothing substance will interact physically with perspiration from the skin and due thereto increase in ability to condition or soothe the skin.” Such limitations are nowhere shown to be taught in the references cited.

As mentioned in detail above, Usala is not concerned with “the inner layer being free of said antimicrobial agent of the outer layer”. Neither Fechner, nor Wollmann, nor Chou provide for the deficiencies as discussed above. Accordingly, for at least these reasons, claim 18 is novel and patentable over the cited references.

Dependent claims 19-23 are novel and nonobvious for at least the same reasons as their base claim 18 and also for the additional elements they each recite. For example, claim 19 recites that “the antimicrobial agent is distributed within the outer layer *and* applied onto the outer layer.”(emphasis added). Milner in view of Fechner, Usala, Wollmann and Chou in no manner teach of such a configuration of a disposable protective glove.

Accordingly, Applicant respectfully requests withdrawal of the rejection of claim 18 and respective dependent claims under Section 103(a).

#### CONCLUSION

The above-discussed remarks are believed to place the present Application in condition for allowance and action towards that effect is respectfully requested. Should the Examiner have


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any questions regarding the above amendments, the Examiner is requested to telephone Applicant's representative at the number listed below.

Respectfully submitted,

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